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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,112	07/11/2006	Michael Wilson	GRT/117-581	9398

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EXAMINER	
MACAULEY, SHERIDAN R	

ART UNIT	PAPER NUMBER
1653	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOMAIL@nixonvan.com
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Office Action Summary	Application No.	Applicant(s)	
	10/575,112	WILSON ET AL.	
	Examiner	Art Unit	
	SHERIDAN MACAULEY	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-27 and 37-41* is/are pending in the application.

4a) Of the above claim(s) *6,13-27,32,33 and 38-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7-12,31,34 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/8/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Responses and amendments were received and entered on April 8, 2011 and July 28, 2011. All evidence and arguments have been fully considered. Claims 2-4, 28-30, 35 and 36 are canceled. Claims 1, 5-27, 31-34 and 37-41 are pending.

Election/Restrictions

2. Claims 13-27, 32-33 and 38-41 are withdrawn due to a previous requirement for restriction/election. Applicant's election of phage 75 as the species of bacteriophage in the reply filed on July 28, 2011 is acknowledged. Due to the results of the search, this requirement for election of species has been withdrawn.

3. Claims 1, 5-12, 31, 34 and 37 are examined on the merits in this Office action.

Response to Declaration under 37 CFR 1.132

4. The declaration under 37 CFR 1.132 filed April 8, 2011 is insufficient to overcome the rejections based upon 35 USC 103 as set forth in the last Office action because: The unexpected results presented in the application are not commensurate in scope with the claims. Applicant states that the composition recited in the claims provides an unexpected advantage over the prior art compositions because the composition provides improved killing of *Staphylococcus* over the antibody-photosensitizer conjugate of the prior art, that the conjugate provides improved killing in all three growth phases, and that the conjugate provides killing in the presence of an antibiotic. Although applicant has shown that there is improved killing with the SnC36-

phage 75 conjugate, applicant has not demonstrated that the improved characteristics would be applicable to all embodiments of the invention encompassed by the claims. For instance, applicant has not provided evidence that the unexpected results would be applicable to all of the strains of bacteriophage recited in the claims. The strains recited in the strains differ in their characteristics, for instance, they have different infectivity ranges and lysogenisation frequencies. One of ordinary skill in the art would be unable to predict whether a bacteriophage with different characteristics would be capable of achieving the unexpected result. Furthermore, the results would depend upon the photosensitizer that is used. In Embleton et al. (the reference to which applicant refers in the instant declaration), applicant states that the killing induced by the phthalocyanine photosensitizer is not affected by growth rate lp. 3694, col. 2, par. 5). Thus, a growth-rate-independent killing using a conjugate of this photosensitizer would not be unexpected to one of ordinary skill in the art, contrary to applicant's assertions based upon the results achieved with the SnC36 photosensitizer. Therefore, applicant's evidence has been fully considered, but it has not been found to be commensurate in scope with the claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 5, 8-12, 31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogset et al. (WO 02/44395; document cited in prior action) in view of Embleton et al. (Journal of Antimicrobial Chemotherapy, 50:857-864; document cited in prior action). The claims recite a composition comprising a conjugate of a photosensitizer selected from a chlorins and phenothiaziniums, such as a tin (IV) chlorin e6 (SnCe6), and a staphylococcal bacteriophage, wherein the photosensitizer is covalently linked to the bacteriophage. The claims further recite that the photosensitizer is present at 0.01 to 200 micrograms per ml, that the bacteriophage is present at 10^5 to

10^{10} pfu per ml, that the composition comprises a source of calcium ions, such as calcium chloride, and that the solution comprises a pharmaceutically acceptable carrier or an additional component, such as a buffer or preservative. Claims 34-36 recite the composition of claims 1-3 wherein the conjugate is capable of specifically binding to target bacteria.

9. Hogset teaches composition comprising a photosensitizing agent attached to a bacteriophage (p. 20, line 21-p.21, line 1). The reference teaches that the two may be attached by a linkage, such as a covalent bond (p. 20, line 21). The reference teaches that the composition may be a solution in a pharmaceutically acceptable carrier and may comprise additional components such as preservatives (p. 38, lines 3-20). Hogset teaches that the photosensitizer may be present at concentrations in the claimed range, e.g., 0.05 micrograms per ml (p. 38, lines 33-35). Hogset teaches that the virus may be suspended in PBS comprising calcium chloride (p. 47, line 31-p. 48, line 12). The reference teaches the administration of 10^3 to 10^{13} pfu per injection, corresponding to, for instance, 10^5, 10^6, 10^{10} viral particles per injection (p. 16, lines 1-12). Hogset does not specifically teach that the bacteriophage is a staphylococcal bacteriophage and does not teach that the photosensitizer is SnCe6.

10. Embleton teaches compositions comprising conjugates of photosensitizers, such as SnCe6, and IgG (abstract). The reference teaches that the conjugate is constructed to selectively target *Staphylococcus aureus* (abstract). The reference also teaches that the photosensitizer is covalently linked to the IgG (p. 859, par. 3), that the composition may be delivered at 25 micrograms per ml (p. 859, Results, par. 1).

11. At the time of the invention, a composition comprising conjugate of a virus, such as a bacteriophage, and a photosensitizer was known, as taught by Hogset. It was further known that conjugates of photosensitizers, such as the chlorin SnCe6, and targeting molecules, such as IgG, could be used to target *Staphylococcus*, as taught by Embleton. One of ordinary skill in the art would have been motivated to combine these teachings because Hogset teaches that chlorin photosensitizers can be coupled with bacteriophage to selectively target specific cell types (p. 20, line 21-p.21, line 1). One would therefore have recognized that a bacteriophage could be used to target *Staphylococcus* in place of the IgG in the method taught by Embleton. One would further have been motivated to prepare a composition with the claimed concentration of bacteriophage because Embleton teaches the delivery of a wide range of pfu per injection site (the reference teaches the administration of 10^3 to 10^{13} pfu per injection, corresponding to, for instance, 10^5, 10^6, 10^{10} viral particles per injection). Furthermore, Hogset teaches that the virus may be suspended in PBS containing calcium chloride. One would have recognized that, since the preparations of Embleton are also prepared in PBS (p. 859, par. 3), a PBS such as the one used in Hogset could have been used in the composition of the combined teachings. One of ordinary skill in the art would have a reasonable expectation of success in combining the claimed teachings because Hogset teaches that many types of photosensitizers and viruses may be conjugated and Embleton teaches techniques for preparing SnCe6 conjugates. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

12. Claims 1, 5, 7-12, 31, 34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogset et al. (WO 02/44395; document cited in prior action) in view of Embleton et al. (Journal of Antimicrobial Chemotherapy, 50:857-864; document cited in prior action) as applied to claims 1, 5, 8-12, 31 and 34 above, and further in view of Norris et al. (US 2004/0220123 A1). The claims recite a composition comprising a conjugate of a photosensitizer, such as a tin (IV) chlorin e6 (SnCe6), and a bacteriophage, such as a staphylococcal bacteriophage. The claims further recite that the staphylococcal bacteriophage is one of those recited in claims 7 and 37, such as phage 75 or phage phi-11. The claims further recite that the photosensitizer is covalently linked to the bacteriophage, that the photosensitizer is present at 0.01 to 200 micrograms per ml, that the bacteriophage is present at 10^5 to 10^{10} pfu per ml, that the composition comprises a source of calcium ions, such as calcium chloride, and that the solution comprises a pharmaceutically acceptable carrier or an additional component, such as a buffer or preservative. Claims 34-36 recite the composition of claims 1-3 wherein the conjugate is capable of specifically binding to target bacteria.

13. Hogset teaches composition comprising a photosensitizing agent attached to a bacteriophage (p. 20, line 21-p.21, line 1). The reference teaches that the two may be attached by a linkage, such as a covalent bond (p. 20, line 21). The reference teaches that the composition may be a solution in a pharmaceutically acceptable carrier and may comprise additional components such as preservatives (p. 38, lines 3-20). Hogset teaches that the photosensitizer may be present at concentrations in the claimed range,

e.g., 0.05 micrograms per ml (p. 38, lines 33-35). Hogset teaches that the virus may be suspended in PBS comprising calcium chloride (p. 47, line 31-p. 48, line 12). The reference teaches the administration of 10^3 to 10^{13} pfu per injection, corresponding to, for instance, 10^5, 10^6, 10^{10} viral particles per injection (p. 16, lines 1-12). Hogset does not specifically teach that the bacteriophage is a staphylococcal bacteriophage and does not teach that the photosensitizer is SnCe6.

14. Embleton teaches compositions comprising conjugates of photosensitizers, such as SnCe6, and IgG (abstract). The reference teaches that the conjugate is constructed to selectively target *Staphylococcus aureus* (abstract). The reference also teaches that the photosensitizer is covalently linked to the IgG (p. 859, par. 3), that the composition may be delivered at 25 micrograms per ml (p. 859, Results, par. 1).

15. At the time of the invention, it would have been obvious to combine Hogset with Embleton to arrive at nearly all of the elements of the claimed invention, as discussed above. Neither of the references, however, teach that the staphylococcal bacteriophage is specifically phage 75 or phage phi-11

16. Norris teaches methods for targeting specific pathogens with toxic agents for the treatment of various infections (abstract). The reference teaches that virion constructs may be prepared to target *Staphylococcus aureus* infections, such as constructs including the phi-11 bacteriophage (pp. 14-15, par. 160, p. 20, par. 212, p. 21, par. 222). One of ordinary skill in the art would be motivated to combine the teachings of Norris with those of Hogset and Embleton because Embleton teaches the desirability of targeting *Staphylococcus aureus* with photosensitizers and Norris teaches that phages

specific for *Staphylococcus aureus,* such as phage phi-11, are desirable tool for targeting these microbes. Since the targeting of specific pathogens using bacteriophage conjugates was known at the time of the invention, as taught by Hogset and Norris, and the use of the claimed photosensitizer for the targeting of *Staphylococcus aureus* was also known, one of ordinary skill in the art would have recognized that the bacteriophage of Norris would have been desirable to target *Staphylococcus aureus* using the photosensitizer system taught by Embleton and Hogset. Norris specifically teaches that bacteriophages are desirable for the targeting of bacteria because they are able to target a specific species in order to deliver a drug (p. 14, par. 159-160). One of ordinary skill in the art would have had a reasonable expectation of success in using the system because Hogset teaches methods for preparing and using bacteriophage-sensitizer conjugates. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

17. Claims 1, 5-12, 31, 34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogset et al. (WO 02/44395; document cited in prior action) in view of Embleton et al. (Journal of Antimicrobial Chemotherapy, 50:857-864; document cited in prior action) as applied to claims 1, 5, 8-12, 31 and 34 above, and further in view of Blair et al. (Bulletin of the World Health Organization, 1961, 24:771-784). The claims recite a composition comprising a conjugate of a photosensitizer, such as a tin (IV) chlorin e6 (SnCe6), and a bacteriophage, such as a staphylococcal bacteriophage. The claims further recite that the staphylococcal bacteriophage is one of those recited in

claims 6, 7 and 37, such as phage 53, phage 75 or phage phi-11. The claims further recite that the photosensitizer is covalently linked to the bacteriophage, that the photosensitizer is present at 0.01 to 200 micrograms per ml, that the bacteriophage is present at 10^5 to 10^{10} pfu per ml, that the composition comprises a source of calcium ions, such as calcium chloride, and that the solution comprises a pharmaceutically acceptable carrier or an additional component, such as a buffer or preservative. Claims 34-36 recite the composition of claims 1-3 wherein the conjugate is capable of specifically binding to target bacteria.

18. Hogset teaches composition comprising a photosensitizing agent attached to a bacteriophage (p. 20, line 21-p.21, line 1). The reference teaches that the two may be attached by a linkage, such as a covalent bond (p. 20, line 21). The reference teaches that the composition may be a solution in a pharmaceutically acceptable carrier and may comprise additional components such as preservatives (p. 38, lines 3-20). Hogset teaches that the photosensitizer may be present at concentrations in the claimed range, e.g., 0.05 micrograms per ml (p. 38, lines 33-35). Hogset teaches that the virus may be suspended in PBS comprising calcium chloride (p. 47, line 31-p. 48, line 12). The reference teaches the administration of 10^3 to 10^{13} pfu per injection, corresponding to, for instance, 10^5, 10^6, 10^{10} viral particles per injection (p. 16, lines 1-12). Hogset does not specifically teach that the bacteriophage is a staphylococcal bacteriophage and does not teach that the photosensitizer is SnCe6.

19. Embleton teaches compositions comprising conjugates of photosensitizers, such as SnCe6, and IgG (abstract). The reference teaches that the conjugate is constructed

to selectively target *Staphylococcus aureus* (abstract). The reference also teaches that the photosensitizer is covalently linked to the IgG (p. 859, par. 3), that the composition may be delivered at 25 micrograms per ml (p. 859, Results, par. 1).

20. At the time of the invention, it would have been obvious to combine Hogset with Embleton to arrive at nearly all of the elements of the claimed invention, as discussed above. Neither of the references, however, teach that the staphylococcal bacteriophage is specifically phage 53, phage 75 or phage phi-11

21. Blair teaches methods for characterizing staphylococci by infecting the bacteria with a variety of staphylococcal phages (abstract). The reference teaches a number of known staphylococcal phages, such as phage 53 and 75 (p. 772, col. 2). One of ordinary skill in the art would be motivated to combine the teachings of Blair with those of Hogset and Embleton because Embleton teaches the desirability of targeting *Staphylococcus aureus* with photosensitizers and Blair teaches that phages specific for *Staphylococcus aureus,* such as phage 53 and phage 75, may be used for targeting these microbes. Since the targeting of specific pathogens using bacteriophage conjugates was known at the time of the invention, as taught by Hogset, and the use of the claimed photosensitizer for the targeting of *Staphylococcus aureus* was also known, one of ordinary skill in the art would have recognized that the bacteriophage of Blair would have been desirable to target *Staphylococcus aureus* using the photosensitizer system taught by Embleton and Hogset. One of ordinary skill in the art would have had a reasonable expectation of success in using the system because Hogset teaches methods for preparing and using bacteriophage-sensitizer conjugates. It would therefore

have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

22. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

23. Applicant's arguments filed April 8, 2011 have been fully considered but they are not persuasive. Applicant argues that the claimed invention is not rendered obvious in view of the cited prior art. Specifically, applicant argues that the Hogset reference does not render the claimed invention obvious because it does not teach the targeting of prokaryotic bacteria. However, it is noted that the reference teaches that the viral carrier molecules (e.g., the phages) may be prepared for use to be selective for various targets at p. 22, lines 6-16 of the specification, and that bacteriophages, which are selective for bacteria, may be used in the instant invention. Thus, the reference does not teach away from the selective targeting of bacteria in the photosensitizer conjugates. Further, the conjugation of a photosensitizer such as those used in the claimed invention to a molecule for the specific targeting of bacteria was known, as taught by Embleton and discussed above. Although applicant argues that Embleton does not teach the specific targeting of a photosensitizer to a bacterium, particularly to *Staphylococcus*, it is noted that the reference teaches that the conjugate is constructed to selectively target *Staphylococcus aureus*, a staphyloccoci. Furthermore, although applicant argues that

the reference do not teach targeting and killing staphylococci, it is noted that the claims do not recite the property of the composition to which applicant refers, i.e., the killing of the bacteria. Therefore, the reference teaches the specific targeting of a bacterium of the species recited in the claims.

24. Although applicant further argues that the claimed invention has unexpected properties that render the claims patentable over the prior art, it is noted that the unexpected results presented in the application are not commensurate in scope with the claims. Applicant states that the composition recited in the claims provides an unexpected advantage over the prior art compositions because the composition provides improved killing of *Staphylococcus* over the antibody-photosensitizer conjugate of the prior art, that the conjugate provides improved killing in all three growth phases, and that the conjugate provides killing in the presence of an antibiotic. Although applicant has shown that there is improved killing with the SnC36-phage 75 conjugate, applicant has not demonstrated that the improved characteristics would be applicable to all embodiments of the invention encompassed by the claims. For instance, applicant has not provided evidence that the unexpected results would be applicable to all of the strains of bacteriophage recited in the claims. The strains recited in the strains differ in their characteristics, for instance, they have different infectivity ranges and lysogenisation frequencies. One of ordinary skill in the art would be unable to predict whether a bacteriophage with different characteristics would be capable of achieving the unexpected result. Furthermore, the results would depend upon the photosensitizer that is used. In Embleton et al. (the reference to which applicant refers in the instant

declaration), applicant states that the killing induced by the phthalocyanine photosensitizer is not affected by growth rate lp. 3694, col. 2, par. 5). Thus, a growth-rate-independent killing using a conjugate of this photosensitizer would not be unexpected to one of ordinary skill in the art, contrary to applicant's assertions based upon the results achieved with the SnC36 photosensitizer. Therefore, applicant's evidence has been fully considered, but it has not been found to be commensurate in scope with the claims.

25. Therefore, applicant's arguments have been fully considered, but they have not been found to be persuasive.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sue Liu can be reached on (571) 272-5539. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A. Davis/
Primary Examiner, Art Unit 1651